

PATENT  
171-613P

## IN THE U.S. PATENT AND TRADEMARK OFFICE

APPLICANT: Takanori OKA  
APPL. NO.: 09/214,723  
FILED: January 11, 1999  
FOR: NUCLEIC ACID ASSAY PROCESS AND ASSAY KIT

GROUP: Unassigned  
EXAMINER: Unassigned

INFORMATION DISCLOSURE STATEMENT  
(SUBMISSION AFTER FILING OF AN APPLICATION  
BUT BEFORE FINAL REJECTION OR NOTICE OF ALLOWANCE  
OR CONCURRENTLY WITH A RULE 53(d) CPA APPLICATION)

Assistant Commissioner for Patents  
Washington, DC 20231

March 3, 1999

Sir:

Pursuant to 37 C.F.R. §§ 1.97 and 1.98, applicant(s) hereby submit(s) an Information Disclosure Statement for consideration by the Examiner.

I. LIST OF PATENTS, PUBLICATIONS OR OTHER INFORMATION

The patents, publications or other information submitted for consideration by the Office are listed on PTO-1449, attached hereto.

II. COPIES (check at least one box)

- a. X Submitted herewith is a legible copy of (i) each U.S. and foreign patent; (ii) each publication or that portion which caused it to be listed; and (iii) all other information or that portion which caused it to be listed.
- b.      Some or all of the documents listed on the PTO-1449 are not enclosed because they were cited in the International Search Report and copies should already be in the PTO file. If copies are needed, please contact the undersigned.

III. CONCISE EXPLANATION OF THE RELEVANCE  
(check at least one box)

a. X DOCUMENTS NOT IN THE ENGLISH LANGUAGE

A concise explanation of the relevance of all patents, publications or other information listed that is not in the English language is as follows:

An English language abstract of Japanese Patent No. JP-A 1-314965/1989 is enclosed herewith. JP-A 1-314965 is also referenced in the present specification at page 15, line 33 and page 20, line 22.

An English language abstract of Japanese Patent No. JP-A 1-252300/1989 is enclosed herewith. JP-A 1-252300 is also referenced in the present specification at page 15, line 34, page 16, line 32, page 20, line 23, and page 21, line 7.

An English language abstract of Japanese Patent No. JP-A 59-93100/1984 is enclosed herewith. JP-A 59-93100 is also referenced at in the present specification at page 18, line 9.

An English language abstract of Japanese Patent No. JP-A 59-204200/1984 is enclosed herewith. JP-A 59-204200 is also referenced at in the present specification at page 18, line 11.

An English language abstract of Japanese Patent No. JP-A 59-148798/1984 is enclosed herewith. JP-A 59-148798 is also referenced in the present specification at page 18, line 11.

The relevancy of EP 0 362 042 B1 can be found in the English language translation of the claims attached hereto. EP 0 362 042 B1 is also discussed in the present specification at page 5, lines 22-37.

A copy of the front page and the last page of WO 95/02068 A1 is attached hereto. The relevancy of WO 95/02068 A1 can be found in the English language abstract on the front page. WO 95/02068 A1 is also discussed in the present specification at page 6, line 18.

b. \_\_\_\_\_ DOCUMENTS IN THE ENGLISH LANGUAGE

All of the patents, publications or other information are in the English language. No statement of relevancy is required.

c.        **ENGLISH LANGUAGE SEARCH REPORT**

An English language version of the search report or action which indicates the degree of relevance found by the foreign office is attached, thereby satisfying the requirement for a concise explanation. See MPEP 609(A)(3).

d.   X   **OTHER**

The following additional information is provided for the Examiner's consideration. The following references are discussed in the present specification as follows:

L. Cremonesi et al., PCR METHODS AND APPLICATIONS, 1:297-298 (1992) is discussed in the present specification at page 4, lines 22-33.

R.K. Saiki et al., NATURE, 324:163-167 (November 13, 1986) is discussed in the present specification at page 4, line 34 to page 5, line 6.

S.M. Kahn et al., ONCOGENE, 6:1079-1083 (1991) is discussed in the present specification at page 5, lines 7-21.

B. Terouanne, ANALYTICAL BIOCHEMISTRY, 205:193-199 (1992) is discussed in the present specification at page 5, line 34.

T. Oka et al., NUCLEIC ACIDS RESEARCH, 22(9):1541-1547 (1994) is discussed in the present specification at page 6, line 18.

K. Ubukata et al., JOURNAL OF CLINICAL MICROBIOLOGY, 30(7):1728-1733 (July 1992) is discussed in the present specification at page 20, line 23

M. A. Innis et al., PCR PROTOCOLS, Academic Press, Inc., pages. 14, 15, 352 and 353 (1990) is discussed in the present specification at page 14, line 22

G. T. Walker et al., DNA PROBES, pages 255-297, 2<sup>nd</sup> Edition, Stockton Press (1993) is discussed in the present specification at page 15, line 5

S. Hirose, Supplementary Volume of Jikken Igaku (Experimental Medicine), Genetic Engineering Handbook, Yodosha, 8, No. 9 (1990) is discussed in the present specification at page 16, lines 12-13.

Applicants also note that the references of B. Terouanne, ANALYTICAL BIOCHEMISTRY, 205:193-199 (1992) and WO 95/02068 A1 were previously listed on the Form PTO-1449 submitted with the Information Disclosure Statement dated January 11, 1999. These references were cited in the International Search Report and should have been received by the Patent Office, however, Applicants are submitting these references for the Examiner's convenience.

FEES

IV. X THIS IDS IS BEING FILED UNDER 37 C.F.R. § 1.97(b):  
(check one box)

- a. X within three months of the filing date of a national application (37 C.F.R. § 1.97(b)(1)). No fee or statement is required.
- b.        within three months of the date of entry of the national stage as set forth in \$1.491 in an international application (37 C.F.R. § 1.97(b)(2)). No fee or statement is required.
- c.        before the mailing date of a first Action on the merits (37 C.F.R. § 1.97(b)(3)). No fee or statement is required. In the event that a first Office Action on the merits has been issued, please consider this IDS under 37 C.F.R. § 1.97(c) and see the statement under 37 C.F.R. § 1.97(e) below, or, if no statement has been made, charge our deposit account in the amount of \$240.00 as required by 37 C.F.R. § 1.17(p).

V.        THIS IDS IS BEING FILED UNDER 37 C.F.R. § 1.97(c):  
(check one box)

before the mailing date of a Final Office Action under 37 C.F.R. § 1.113 (See 37 C.F.R. § 1.97(c)(1)) or before the mailing date of a Notice of Allowance under 37 C.F.R. § 1.311 (See 37 C.F.R. § 1.97(c)(2)).

- a.        No statement; therefore, a fee in the amount of \$240.00 as required by 37 C.F.R. § 1.17(p).
- or
- b.        See the statement below. No fee is required.

VI. STATEMENT UNDER 37 C.F.R. § 1.97(e) (check only one box)

The undersigned hereby states that

- a. ☐ each item of information contained in the IDS was cited in a communication from a foreign Patent Office in a counterpart foreign application not more than three months prior to the filing of this IDS; or
- b. ☐ no item of information contained in the IDS was cited in a communication from a foreign Patent Office in a counterpart foreign application and, to the best of my knowledge after making reasonable inquiry, was known to any individual designated in 37 C.F.R. § 1.56(c) more than three months prior to the filing of this statement.
- c. ☐ Some of the items of information were cited in a communication from a foreign Patent Office. As to this information, the undersigned states that each item of information contained in the IDS was cited in a communication from a foreign Patent Office in a counterpart foreign application not more than three months prior to the filing of this IDS. As to the remaining information, the undersigned hereby states that no item of this remaining information contained in the IDS was cited in a communication from a foreign Patent Office in a counterpart foreign application and, to the best of my knowledge after making reasonable inquiry, was known to any individual designated in 37 C.F.R. § 1.56(c) more than three months prior to the filing of this statement.

VII. PAYMENT OF FEES (check one box)

- ☐ A check in the amount of \$240.00 as required by 37 C.F.R. § 1.17(p) is enclosed for the above-identified fee.
- ☐ Please charge Deposit Account No. 02-2448 in the amount required by 37 C.F.R. § 1.17(p) for the above-indicated fee. A triplicate copy of this paper is attached.

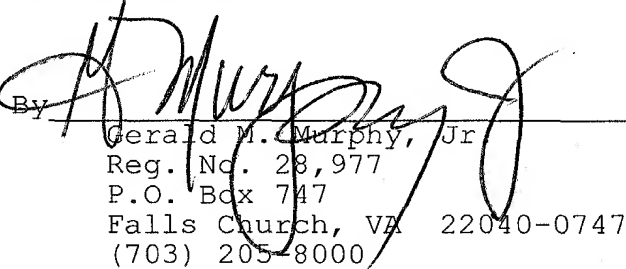
X No fee is required.

If the Examiner has any questions concerning this IDS, he/she is requested to contact the undersigned. If it is determined that this IDS has been filed under the wrong rule, the PTO is requested to consider this IDS under the proper rule (with a petition if necessary) and charge the appropriate fee to Deposit Account No. 02-2448.

If necessary, the Commissioner is hereby authorized in this, concurrent, and future replies, to charge payment or credit any overpayment to Deposit Account No. 02-2448 for any additional fees required under 37 CFR \$1.16 or under \$1.17; particularly, extension of time fees.

Respectfully submitted,

BIRCH, STEWART, KOLASCH & BIRCH, LLP

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Enclosures: X PTO-1449  
X Documents  
\_\_\_\_ Foreign Search Report  
\_\_\_\_ Fee  
\_\_\_\_ Other:

(Rev. 6/15/98)  
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